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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/057,323
Filing Date: January 25, 2002
Appellant(s): DAVIS ET AL.

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EXAMINER'S ANSWER

This is in response to the appeal brief filed April 18, 2006 appealing from the Office action mailed November 22, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,846,966 Rosenblum et al. 12-1998

The Medical Letter on Drugs and Therapeutics, 1998, 40;1030:68-69

Katzung, Basic and Clinical Pharmacology, 6th ed.,1995, page 529

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 11-13, 37-40, 42, 43, 47-48, 83-84, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenblum et al. (US Patent 5,846,966) and Medical Letter (The Medical Letter on Drugs and Therapeutics, 1998, 40;1030:68-69), references of record.

Rosenblum et al. also teaches the elected compound herein, ezetimibe, useful for reducing cholesterol and the risk of artherosclerosis (See the abstract, also col. 32, Example 6, Compound 6A, and col. 40, line 52 particularly).

Medical Letter teaches fenofibrate as useful in reducing serum cholesterol level (See page 68 – 69).

The references do not expressly teach a composition containing fenofibrate and ezetimibe together.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate both ezetimibe and fenofibrate together in a single composition.

One of ordinary skill in the art would have been motivated to incorporate both ezetimibe and fenofibrate together in a single composition. The prior art teaches that both ezetimibe and fenofibrate as useful in reducing serum cholesterol individually. Therefore, combining two agents, which are known to be useful to reduce serum cholesterol individually, into a single composition useful for the very same purpose is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069).

Claims 21, 28, 32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenblum et al. and Medical Letter as applied to claims 1-4, 11-13, 21, 28, 32, 34, 37-40, 42, 43, 47-48, 83, 86, and 100-101 above, and further in view of Katzung (Basic & Clinical Pharmacology, 6th ed., 1995, page 529), references of record.

Rosenblum et al. and Medical Letter suggest a composition containing fenofibrate and ezetimibe.

Rosenblum et al. and Medical Letter do not expressly teach the composition contains niacin.

Katzung teaches niacin as useful for lowering cholesterol (See page 529, col. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate niacin into the fenofibrate – ezetimibe composition.

One of ordinary skill in the art would have been motivated to incorporate niacin into the fenofibrate – ezetimibe composition. All three ingredients, i.e., niacin, fenofibrate, and ezetimibe, are known as useful in reducing cholesterol. Therefore, combining two or more agents, which are known to be useful to reduce serum cholesterol individually, into a single composition useful for the very same purpose is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069).

Claims 100 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenblum et al. (US Patent 5,846,966) and Katzung, references of record.

Rosenblum et al. also teaches the elected compound herein, ezetimibe, useful for reducing cholesterol and the risk of artherosclerosis (See the abstract, also col. 32, Example 6, Compound 6A, and col. 40, line 52 particularly).

Katzung teaches niacin as useful for lowering cholesterol (See page 529, col. 1).

The references do not expressly teach a composition containing niacin and ezetimibe together.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate both ezetimibe and niacin together in a single composition.

One of ordinary skill in the art would have been motivated to incorporate both ezetimibe and niacin together in a single composition. The prior art teaches that both ezetimibe and niacin as useful in reducing serum cholesterol individually. Therefore, combining two agents, which are known to be useful to reduce serum cholesterol individually, into a single composition useful for the very same purpose is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069).

(10) Response to Argument

Appellant's arguments in page 8-9 of the Brief filed April 18, 2006 averring the cited prior arts failing to provide motivation to combine the herein claims ingredients into a single composition are unconvincing. The motivation to combine is based on the fact that the herein claimed agents are useful to reduce serum cholesterol individually, although one agent may be more effective than the other, which is expected. It flows logically to combine two or more old and well-known agents, known to be useful as

cholesterol-reducing agents, into a single composition useful for the very same purpose (See *In re Kerkhoven* 205 USPQ 1069).

Appellant's arguments in page 10 of the Brief filed April 18, 2006 averring Medical letters teaches the LDL lowering activities of fenofibrate is not as effective as statins are not convincing. The fact is that fenofibrate can effectively reducing LDL cholesterol, in addition with its triglyceride lowering activities. Whether it is less effective in lowering cholesterol when comparing to the statins is irrelevant to the ground of rejections set forth in the previous office action mailed November 22, 2005. As discussed there and above, the motivation to combine is based on the fact that the herein claimed agents are useful to reduce serum cholesterol individually. It flows logically to combine two or more old and well-known agents, known to be useful as cholesterol-reducing agents, into a single composition useful for the very same purpose (See *In re Kerkhoven* 205 USPQ 1069).

Appellant's arguments in page 11-12 of the Brief filed April 18, 2006 averring the potential drug-drug interaction between fenfibrate and statins are not convincing. Examiner respectfully points out that the appellant incorrectly characterizes the teachings in Medical Letter. The teachings in the whole paragraph in Medical Letter, page 69 states,

> "Like other fibrates, fenofibrate potentiates the effects of oral anticoagulants. Whether, like gemfibrozil and niacin, it could increase the risk of rhabdomyolysis when taken concurrently with statin is unclear." (Page 69, Drug Interactions Section in Medical Letter)

The paragraph teaches that fenofibrate can potentiate the effects of oral anticoagulants. However, whether fenofibrate will potentiate the risk of rhadomyolysis, just like gemfibrozil and niacin will when taken concurrently with statin, when taken concurrently with statin is unclear. Therefore, one of ordinary skill in the art should be clear from the teachings above is that 1) fenofibrate will potentiate the effects of oral coagulants; 2) it is not known whether fenofibrate will potentiate the risk of rhadomyolysis when concurrently taken with statins; 3) Gemfibrozil and niacin can increase the risk of rhadomyolysis when concurrently taken with statins. The passage does not disclose information as to the interaction between niacin and fenofibrate. Therefore, the teachings cannot be a probative evidence for refuting Examiner's rejection set forth in the previous office action mailed November 22, 2006.

Appellant argues unconvincingly, in two incidences: in page 12-13 and pages 14-15 of the Brief filed April 18, 2006 averring no motivation or suggestions being provided from the cited prior arts. As discussed there and above, the motivation to combine is based on the fact that the herein claimed agents are useful to reduce serum cholesterol individually. It flows logically to combine two or more old and well-known agents, known to be useful as cholesterol-reducing agents, into a single composition useful for the very same purpose (See *In re Kerkhoven* 205 USPQ 1069).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

San-ming Hui
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Art Unit 1617

Conferees:

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PRIMARY EXAMINER

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER